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| 10/633,349 | 08/01/2003 | Donald A. Sargent | ST8725US | 3719 |

22203 7590 03/08/2006
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EXAMINER

CHORBAJI, MONZER R

ART UNIT PAPER NUMBER

1744

DATE MAILED: 03/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/633,349 | SARGENT ET AL. | |
| | Examiner | Art Unit | |
| | MONZER R. CHORBAJI | 1744 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 16-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 24 and 25 is/are allowed.
- 6) ☒ Claim(s) 1-13 and 16-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This final action is in response to the amendment received on 11/30/2005

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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4. Claims 1-13 and 16-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malchesky (U.S.P.N. 5,552,115) in view of Bond et al (U.S.P.N. 4,445,551).

With respect to claims 1, 7 and 12, the Malchesky reference teaches the following: a container (figure 4:C) with a generally cup-shaped tray that includes a bottom wall and a continuous side wall, bottom and side walls defining a cavity (figure 4:62, 60, col.6, lines 64-67 and col.7, lines 1-6), a lid attachable to the tray, a fluid inlet in the tray communicating with the cavity (figure 4:72), a fluid outlet in the tray communicating with the cavity (figure 4:70) where each of the inlet and the outlet has a valve assembly (figure 4:74) such that when the tray is placed in the decontamination chamber (figure 2:10 and lid B in figure 1), the valves allow liquid sterilant to enter and exit the tray and when the tray is removed from the decontamination chamber the valves seal the container (col.7, lines 5-6, lines 26-30) and a circulation system (col.6, lines 24-27) such that the cavity is in communication with the circulation system through the valves when the container is placed in the decontamination chamber. However, with respect to claims 1, 7 and 12, the Malchesky reference fails to teach using a flexible valve element having a movable part and a fixed part in the container that is moved by a mechanical actuator in the decontamination chamber. The Bond reference, which is in the art of transferring liquids between different enclosures, teaches placing a movable valve (figure 4:22, 21 and col.8, lines 17-26) on a container (col.8, lines 10-13) such that using a mechanical actuator (figure 10:70 and col.6, lines 40-44) axially moves the valve (figure 10: 36 and 73 and figures 11-12). In addition, the flexible valve element

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includes a first portion (figure 4:22) movable relative to the container (figure 9:B) and a second portion (figure 2:21) fixed relative to the container (figure 9:B). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of the Malchesky reference by substituting one liquid transfer means (check valves) for another (movable actuated valves) since both of the movable valve and the mechanical actuator can be molded from plastic and this constitutes an economic advantage (Bond et al., col.2, lines 21-22).

With respect to claims 13 and 19-20, the Malchesky reference teaches the following: a circulation system (col.6, lines 24-27) with a first fluid inlet line (figure 2:32) and a fluid outlet line (figure 3:36) that communicates with the first fluid inlet port (figure 4:72) and the fluid outlet port (figure 4:70) of a container (figure 4 C) when the container is disposed in the decontamination chamber (col.7, lines 5-6, lines 26-30), a microbial liquid decontamination solution (col.5, lines 53-55) and an essentially closed loop circulation system for circulating the liquid sterilant (col.6, lines 24-27).

With respect to claims 2, 5-6, 8-9, 16 and 21, the Malchesky reference discloses a tray with multiple inlets and an outlet (figure 4:72 and 70) where each inlet and outlet includes check valve (figure 4:74), but fails to teach the following: flexible valve element with first portion movable relative to the tray and the second portion is fixed to the tray, each of the flexible valve elements is formed of a resilient flexible material, valve assembly is movable by an actuator element on the decontamination chamber, valve assembly includes a flexible valve element having a normally closed position, each actuator physically contacts the first movable portion of the flexible valve element and

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moves it to the open position when the container is placed in the decontamination chamber and a second fluid inlet with a flexible valve element. With respect to claims 2, 5-6, 8-9, 16 and 21, the Bond reference teaches the following: a flexible valve element having a first portion movable (figure 4:22) relative to the container (figure 9:B) and a second portion fixed (figure 2:21) to the container (figure 4:22, figure 3:22 and 24 and col.8, lines 17-26), each of the flexible valve elements is formed of a resilient flexible material (col.3, lines 20-23), valve assembly is independently movable by an actuator element on the container (figure 10:70, col.6, lines 40-44 and col.8, lines 10-13) between an open position and a closed position in order for the fluid to be transferred, valve assembly includes a flexible valve element having a normally closed position (col.6, lines 18-20) and each actuator physically contacts the first movable portion (figure 4:22) of the flexible valve element (figure 6:21 and 22) and moves it to the open position (col.8, lines 17-26 and figure 10:70). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of the Malchesky reference by substituting one liquid transfer means (check valves) for another (movable actuated valves) since both of the movable valve and the mechanical actuator can be molded from plastic and this constitutes an economic advantage (Bond et al., col.2, lines 21-22).

With respect to claims 3-4, 10 and 17-18, the Malchesky reference discloses a tray with multiple inlets and an outlet (figure 4:72 and 70) where each inlet and outlet includes check valve (figure 4:74) such that when the tray is placed in the decontamination chamber (figure 2:10 and lid B in figure 1), the valves allow liquid

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sterilant to enter and exit the tray (figure 4:C) and when the tray is removed from the decontamination chamber the valves seal the container (col.7, lines 5-6, lines 26-30). This means that when the tray is not in the decontamination chamber, the valve elements are normally in a closed position and when the tray is placed in the decontamination chamber the valves are in an open position; however, the Malchesky reference fails to teach the use of flexible valve elements and that each of the flexible valve elements has a first movable portion that is moved by an external flexible actuator element. With respect to claims 3-4, 10 and 17-18, the Bond reference teaches the use of flexible valve elements (figure 4:22, figure 3:22 and 24, col.8, lines 17-26 and col.3, lines 20-23) and that each of the flexible valve elements has a first movable portion (figure 4:22) that is moved by an external flexible actuator element (figure 10:70). In addition, the Bond reference teaches that the plastic actuator element can be a part of a standard threaded connector (col.6, lines 42-44). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of the Malchesky reference by substituting one liquid transfer means (check valves) for another (movable actuated valves) since both of the movable valve and the mechanical actuator can be molded from plastic and this constitutes an economic advantage (Bond et al., col.2, lines 21-22).

With respect to claims 11 and 22-23, the Malchesky reference teaches the following: a container (figure 4:C) with an inlet and an outlet such that each has a check valve (figure 4:72, 70 and 74), a fluid inlet is in communication with a nozzle within the

container (col.7, lines 38-41) and fluid inlet is in fluid communication with fluid connectors connectable with medical instruments in the container (col.7, lines 30-35).

Remarks

5. The 112, paragraph II rejection made in the action dated 07/27/2005 has been withdrawn since the applicant has pointed out where feature "normally" was disclosed in the specification. Thus, the meaning of such a feature is now clear and precise.

Allowable Subject Matter

6. Claims 24-25 are allowed.

Response to Arguments

7. Applicant's arguments filed on 11/30/2005 have been fully considered but they are not persuasive.

On page 13 of the Remarks section, applicant argues that, "Neither the Malchesky reference or the Bond et al. reference teach, suggest, or show a flexible valve element having a first portion movable relative to said tray and a second portion fixed relative to said tray as required by claims 1, 7, and 12. Further, neither reference teaches the benefits of such a structure." The examiner disagrees. The Bond reference teaches a flexible valve element made up of a first portion movable (figure 4:22) relative to the container (figure 9:B) and a second portion fixed relative (figure 2:21) to the container (figure 9:B). Clearly one having ordinary skill in the art guided by reading the Bond reference at the time the invention was made modify the apparatus of the Malchesky reference by substituting one liquid transfer means (check valves) for another (movable actuated valves) since both of the movable valve and the mechanical

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actuator can be molded from plastic and this constitutes an economic advantage (Bond et al., col.2, lines 21-22).

On bottom of page 13 to the top of page14, of the Remarks section, applicant argues that, "These surfaces are not exposed to the liquid disinfectant, thus may not be suitably microbially deactivated and may ultimately recontaminate the medical instruments." The examiner recognizes that such features the applicant recites are not disclosed in the instant claims. In addition, as the rejection stands with respect to independent claims 1, 7 and 12, the movable actuated valve of the Bond reference upon being substituted for the check valve of the Malchesky reference is capable of being exposed to the sterilant.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

9. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R. CHORBAJI whose telephone number is (571) 272-1271. The examiner can normally be reached on M-F 9:00-5:30.

11. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, GLADYS J. CORCORAN can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Monzer R. Chorbaji
Patent Examiner
AU 1744
02/23/2006

MRC

GLADYS J. CORCORAN
GLADYS J. CORCORAN
PRIMARY EXAMINER